

File No: BIO/CT/24/000139  
Government of India  
Directorate General of Health Services  
Central Drugs Standard Control Organization  
(Biological Division)

**FORM CT-06**

(See rules 22, 25, 26, 29 and 30)

**PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR INVESTIGATIONAL NEW DRUG**

The Central Licencing Authority hereby permits M/s Zydus Lifesciences Limited, Plot Survey No. 23, 25/P, 37, 40/P, 42 to 47, 49 & 50, Sarkhej-Bavla N. H. No. 8A, Opp. Ramdev Masala, Village: Changodar, Taluka - Sanand, Dist.: Ahmedabad, Gujarat (India) -382213 to conduct clinical trial of the new drug or investigational new drug as per protocol number: ZMMR.24.001, Version No.: 01 dated 07.10.2024 in the below mentioned clinical trial sites.

**CT No.: CT- 09/2025**

2. Details of new drug or investigational new drug and clinical trial site [As per Annexure].
3. This permission is subject to the conditions prescribed in part A of Chapter V of the New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act, 1940.

Place: New Delhi  
Date:

(Dr. Rajeev Singh Raghuvanshi)  
Drugs Controller General (India)  
Central Licencing Authority

**Annexure: Details of New Drug or Investigational New Drug:**

|   |  |   |                                |   |                                |  |                                |
|---|--|---|--------------------------------|---|--------------------------------|--|--------------------------------|
| Name of the new drug or investigational new drug:   | Measles, Mumps and Rubella vaccine (Live) I.P. (Freeze Dried)  |   |                                |   |                                |  |                                |
| Therapeutic class:  | Vaccine  |   |                                |   |                                |  |                                |
| Dosage form:  | Freeze dried vaccine for subcutaneous injection upon reconstitution.   |   |                                |   |                                |  |                                |
| Composition:  | <p>Composition:</p> <p>Each dose of 0.5 ml after reconstitution contains:</p> <table border="1"><tr><td>Live Attenuated Measles Virus (Edmonston Zagreb Strain) (Propagated on Human Diploid Cells)</td><td>NLT 1000<br/>CCID<sub>50</sub></td></tr><tr><td>Live Attenuated Mumps Virus (Hoshino Strain) (Propagated on Chick Fibroblast Cells)</td><td>NLT 5000<br/>CCID<sub>50</sub></td></tr><tr><td>Live Attenuated Rubella Virus (RA 27/3 strain) (Propagated on Human Diploid Cells)</td><td>NLT 1000<br/>CCID<sub>50</sub></td></tr></table> <p>Diluent for reconstitution: Sterile Water for Injections I.P.<br/>Excipient: In the formulation of Measles, Mumps and Rubella Vaccine (Live) I.P. (Freeze Dried), all the active ingredients are formulated with Stabilizer 176 and diluent Medium 199. Stabilizer 176 contains the following excipients:<br/>Gelatin, D-Sorbitol, Lactose monohydrate, Lactalbumin hydrolysate, Calcium gluconate monohydrate, L-Alanine, L-Histidine and Tricine. pH of the Stabilizer 176 is adjusted with Sodium hydroxide.</p> | Live Attenuated Measles Virus (Edmonston Zagreb Strain) (Propagated on Human Diploid Cells) | NLT 1000<br>CCID <sub>50</sub> | Live Attenuated Mumps Virus (Hoshino Strain) (Propagated on Chick Fibroblast Cells) | NLT 5000<br>CCID <sub>50</sub> | Live Attenuated Rubella Virus (RA 27/3 strain) (Propagated on Human Diploid Cells) | NLT 1000<br>CCID <sub>50</sub> |
| Live Attenuated Measles Virus (Edmonston Zagreb Strain) (Propagated on Human Diploid Cells) | NLT 1000<br>CCID <sub>50</sub>   |   |                                |   |                                |  |                                |
| Live Attenuated Mumps Virus (Hoshino Strain) (Propagated on Chick Fibroblast Cells)         | NLT 5000<br>CCID <sub>50</sub>   |   |                                |   |                                |  |                                |
| Live Attenuated Rubella Virus (RA 27/3 strain) (Propagated on Human Diploid Cells)          | NLT 1000<br>CCID <sub>50</sub>   |   |                                |   |                                |  |                                |
| Presentation:   | 0.5mL single & 5mL (10 dose) vials   |   |                                |   |                                |  |                                |
| Indication(s):  | For active immunization against measles, mumps, and rubella.   |   |                                |   |                                |  |                                |

**Details of clinical trial sites-**

| S. No. | Name and Address of Clinical Trial Site   | Ethics Committee details   | Name of Principal Investigator |
|--------|---|--|--------------------------------|
| 1      | Medical College & Hospital, Kolkata, 88, College Street, Kolkata - 700073, West Bengal. | Institutional Ethics Committee for Human Research, Medical College, Kolkata, 88, College Street, Kolkata - 700073, West Bengal<br>(ECR/287/Inst/WB/2013/RR-19) | Dr Kalpana Datta               |

|   |  |   |                          |
|---|--|---|--------------------------|
| 2 | Niloufer Hospital Affiliated to Osmania Medical College, RedHills, Lakdikapul, Hyderabad, Telangana-500004.                                  | Institutional Ethics Committee, Osmania Medical College, Koti, Hyderabad-500059, Telangana ECR/300/Inst/AP/2013/RR-24   | Dr N Ravi Kumar          |
| 3 | Department of Paediatrics. Government Medical College and Government General Hospital, Srikakulam- 532001, Andhra Pradesh                    | Institutional Ethics Committee Government Medical College and Government General Hospital, Srikakulam- 532001, Andhra Pradesh ECR/492/Inst/AP/2013/RR-20                    | Dr Jyotsna Seepana       |
| 4 | GMERS Medical College and Civil Hospital, Near Gujarat High Court, S.G. Highway, Sola, Ahmedabad - 380060, Gujarat                           | Institutional Ethics Committee GMERS Medical College & Hospital, Sola, S.G. Highway, Near Gujarat High Court, Ahmedabad- 380060, Gujarat, ECR/404/Inst/GJ/2013/RR-20)       | Dr. Nehal Pate           |
| 5 | Department of Community Medicine and Family Medicine, All India Institute of Medical Sciences, Sijua, Patrapada Bhubaneswar- 751019, Odisha. | Institutional Ethics Committee, All India Institute of Medical Sciences, Sijua, Patrapada, Bhubaneswar-751019, Odisha ECR/534/Inst/OD/2014/RR-20                            | Dr Swayam Pragyna Parida |
| 6 | Department of Paediatrics, LLR Hospital, GSVM Medical College, Swaroop Nagar, Kanpur-208002, Uttar Pradesh.                                  | Ethics Committee, GSVM Medical College, GSVM Medical College, Swaroop Nagar, Kanpur-208002, Uttar Pradesh ECR/680/Inst/UP/2014/RR-20  | Dr Yashwant Kumar Rao    |
| 7 | Department of Paediatrics, Sardar Vallabhbhai Patel Post Graduate Institute of Paediatrics, Oriya Bazar, Cuttack- 753002, Odisha             | Ethics committee, SCB MCH, Cuttack ECR/84/Inst/OR/2013/RR-20  | Dr Pravakar Mishra       |
| 8 | King George's Medical University, Shahmeena Road, Chowk, Lucknow- 226003, Uttar Pradesh.   | Institutional Ethics Committee, Office of Research Cell, Administrative Block, King George's Medical University, Lucknow- 226003, Uttar Pradesh ECR/262/Inst/UP/2013/RR-19) | Dr. Shakal Narayan Singh |
| 9 | Sheth Vadilal Sarabhai General Hospital and Sheth Chinai Maternity Hospital, Ellisbridge, Paldi, Ahmedabad- 380006, Gujarat                  | Institutional Ethics Committee, Aatman Hospital, 5, Anveshan Row house, opp. Umiya mata mandir, Bopal-Ghuma Main Road, Bopal, Ahmedabad-                                    | Dr. Shruti Desa          |

|    |  |   |                        |
|----|--|---|------------------------|
|    |  | 380058, Gujarat<br>(ECR/1565/Inst/GJ/2021)  |                        |
| 10 | Dr. Ram Manohar Lohia Institute of Medical Sciences, Vibhuti Khand, Gomti Nagar, Lucknow Uttar Pradesh -226010.  | Institutional Ethics Committee, Dr. Ram Manohar Lohia Institute of Medical Sciences, Vibhuti Khand, Gomti Nagar, Lucknow - 226010, Uttar Pradesh<br>ECR/913/Inst/UP/2017/RR-20  | Dr Neha Thakur Rai     |
| 11 | Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer Ajmer Rajasthan – 305001   | Institutional Ethics Committee, Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer-305001, Rajasthan, India.<br>ECR/1151/Inst/RJ/2018/RR-2022  | Dr Jai Prakash Narayan |
| 12 | Manglam Plus Medicity Hospital, Sector-5, Shipra Path, Mansarovar, Jaipur Rajasthan-302020.  | IEC Manglam Medicity Hospital, Manglam Plus Medicity Hospital, Sector-5, Shipra Path, Mansarovar, Jaipur- 302020, Rajasthan<br>EC/NEW/INST/2021/13118   | Dr Mohit Poddar        |
| 13 | KLES Dr Prabhakar Kore Hospital & Medical Research Centre, Nehrunagar, Belagavi - 590010, Kamataka   | Institutional Ethics Committee, KLE University, KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehrunagar, Belagavi - 590010, Karnataka<br>ECR/211/Inst/KA/2013/RR-19  | Dr Mahantesh Patil     |
| 14 | Department of Pediatrics, Bharati Vidyapeeth Medical College Hospital and Research Center, Pune-Satara Road, Katraj Dhankawadi, Pune 411043, Maharashtra | Institutional Ethics Committee Bharati Vidyapeeth Deemed University, Bharati Vidyapeeth Medical College Hospital and Research Center, Pune-Satara Road, Katraj Dhankawadi, Pune-411043, Maharashtra<br>ECR/313/Inst/MH/2013/RR-19 | Dr Neeta Hanumante     |

In addition to point 3, the permission is subject to following conditions:

1. The clinical trial should be conducted as per approved protocol titled "A prospective, randomized, parallel, single-blind, two-arm, active controlled, multicentre, Phase IV clinical trial to evaluate the immunogenicity and safety of Measles, Mumps, and Rubella vaccine (Live) I.P. (Freeze Dried) of M/s. Zydus Lifesciences Ltd. compared to Measles, Mumps, and Rubella vaccine (Live) I.P. (Freeze Dried) of M/s. Serum Institute of India Pvt. Ltd. in healthy infants aged 9-12 months". Protocol no. ZMMR.24.001, Version No.: 01 dated 07.10.2024.
2. The firm is required to constitute a DSMB to review the safety data.
3. Firm is required to submit Ethics Committee approval to Phase-IV clinical trial
4. Only CDL, Kasauli certified vaccines already approved for manufacturing & marketing shall be used in the Phase-IV clinical trial in India.
5. Firm needs to submit the complete bio analytical method validation report of anti-measles, Anti-mumps and anti-rubella IgG antibody assays prior to initiating the immunogenicity analysis of clinical trial samples at the Central Laboratory.

Place: New Delhi

Date:

(Dr. Rajeev Singh Raghuvanshi)  
Drugs Controller General (India)  
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